JUN 2 4 2011

K110566

510(k) Summary

(per 21 CFR 807.92(c))

1. Applicant

Reflexonic, LLC
5504 Skye Avenue
Chambersburg, PA 17202

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Date Prepared: February 28, 2011

2. Device Name and Classification

Viberect™ Penile Vibratory Stimulation Device

Primary	
Device:	vibrator for therapeutic use, genital
Regulation Description:	Genital vibrator for therapeutic use.
Product Code:	KXQ
Regulation Number:	884.5960
Classification:	2
Panel:	Obstetrics/Gynecology

Secondary	
Device:	monitor, penile tumescence
Regulation Description:	Unclassified (Pre-Amendment)
Product Code:	LIL
Regulation Number:	Unclassified (Pre-Amendment)
Classification:	Unclassified (Pre-Amendment)
Panel:	Gastroenterology/ Urology

3. Predicate Devices

The Viberect™ Penile Vibratory Stimulation Device is substantially equivalent to the following devices:

510(k) Number	Device	Manufacturer
K851646	Vibrector	Multicept APS

510(k) Number	Device	Manufacturer
K955589	Ferticare Personal Therapeutic Vibrator	Multicept APS

4. Description of the Device

The Viberect™ Penile Vibratory Stimulation Device is a hand held medical device intended for use by the person at home for the purpose of stimulating the nerves of the penis, as a form of sexual aid, or for the purpose of activating several nerve reflexes that men are born with which are responsible for initiation of penile erection and rigidity. This device is unique in that it has two gentle vibrating motors that allow simultaneous vibratory stimulation of both the upper and lower surfaces of the penis. As each side of the male penis is supplied by different nerves, simultaneous stimulation of the upper and lower surfaces increases sexual response.

The device is held by one hand easily, like holding a hair straightener. The penis is placed between the vibrating gel pads, made up of polyurethane soft pads. As pressure is increased to the device, it is automatically activated. The device can be deactivated by releasing the hand pressure which immediately shuts off the vibrating heads. Therefore, the user activates and deactivates the device by hand pressure alone (i.e., no switches need to be pushed). Vibratory stimulation for approximately 7-10 minutes is recommended. The touch pad provides further control by the user whereby the user can increase and decrease the frequency of vibration according to comfort and response. Finally, there are individual modes for the vibratory movement of the upper housing only, lower housing only, and both. The device is powered by rechargeable batteries.

5. Indications for Use (IFU)

Viberect device is a hand held medical device indicated to provoke erections for men who experience erectile dysfunction and to provoke ejaculation for spinal cord injured men.

6. Summary of Performance Data

Biocompatibility Testing

Biocompatibility testing was performed to validate the patient contacting material (Thermoplastic Polyurethane) used for the Viberect™ Penile Vibratory Stimulation. These tests were conducted in accordance with USP *In Vivo* Biological Reactivity Tests (Class VI Plastics Tests) and included Intracutaneous and Systemic Toxicity testing plus Five Day Implant testing. The polyurethane was shown to be nontoxic and did not cause an adverse reaction when implanted for five days.

Performance Testing – Bench Studies

The Viberect has been shown to be substantially equivalent to the predicate device, the Ferticare Personal Therapeutic Vibrator (K955589), in terms of actual penile stimulation (i.e., amount of penis actually stimulated) for spinal cord Injured men. In addition, a comprehensive Risk Analysis confirmed that the benefits of the Viberect Device outweigh all potential risks.

7. Safety & Effectiveness

The Viberect™ Penile Vibratory Stimulation Device is substantially equivalent to the predicate devices listed in this 510(k) submission. More specifically, the IFU of the Viberect encompasses those listed for the predicate devices as it both provokes penile erection and ejaculation in men with erectile dysfunction and men with spinal cord injuries which inhibit these functions. In addition, all three devices utilize penile vibratory stimulation and any differences in technological characteristics between the Viberect™ Penile Vibratory Stimulation Device and the predicate devices do not raise issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

Reflexonic, LLC
c/o Ms. Caroline Tontini
Emergo Group, Inc.
611 West 5th Street
Third Floor
AUSTIN TX 78701

JUN 24 2011

Re: K110566
Trade/Device Name: Viberect™ Penile Vibratory Stimulation Device
Regulation Number: 21 CFR §884.5960
Regulation Name: Genital vibrator for therapeutic use
Regulatory Class: II
Product Code: KXQ
Dated: June 2, 2011
Received: June 9, 2011

Dear Ms. Tontini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110566

Device Name: Viberect™ Penile Vibratory Stimulation Device

Indications for Use:

Viberect™ Penile Vibratory Stimulation Device is a hand held medical device indicated to provoke erections for men who experience erectile dysfunction and to provoke ejaculation for spinal cord injured men.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110566